



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

New England District

95058d

One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 596-7700  
FAX: (781) 596-7896

**WARNING LETTER  
NWE-35-04W**

**VIA FEDERAL EXPRESS**

September 21, 2004

Liberato Mancaniello, President  
Maria's Gourmet Pasta Products Inc.  
245 Ferry Street  
Malden, MA 02148-7112

Dear Mr. Mancaniello,

On July 12, 15, 2004 we inspected your seafood processing facility, located at 245 Ferry Street, Malden, MA 02148. We found that you have a serious deviation from the Seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your lobster and snow crab ravioli is adulterated in that the product has been prepared packed or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in the FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviation is as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are

reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (b). However your firm does not have a HACCP plan for lobster and snow crabmeat ravioli products. Your firm handles frozen vacuum packaged cooked lobster meat and frozen vacuum packaged cooked snow crabmeat to be used in your final ravioli products. Your process involves thawing the meats while still sealed in the vacuum package (i.e. prior to breaking the vacuum seal). This practice may create a potential for *Clostridium botulinum* pathogen growth and toxin formation

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from the receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You should include in your response documentation such as a HACCP plan for lobster and snow crab ravioli, or any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation, and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Anthony P. Costello, Compliance Officer, 1 Montvale Avenue, Stoneham, MA 02180. If you have questions regarding any issue in this letter please contact me at **781.596.7716**.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gary T. Costello', is written over a printed name.

Gary T. Costello  
District Director  
New England District Office